March 6, 2026

Lucius Long
Zhejiang Chuangxiang Medical Technology Co., LTD.
Room 101-1, 201-1, 301, 401, Building 50
No.650 Hongfeng Road, Donghu Street, Linping District
Hangzhou, 311100
China

Re: K253132
Trade/Device Name: Single use stone retrieval balloons
Regulation Number: 21 CFR 876.5010
Regulation Name: Biliary Catheter And Accessories
Regulatory Class: Class II
Product Code: FGE
Dated: February 3, 2026
Received: February 3, 2026

Dear Lucius Long:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the Medical Device File (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

ANTHONY LEE -S

Anthony C. Lee Ph.D., M.B.A.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal, Obesity, and Transplant Devices
OHT3: Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253132

Please provide the device trade name(s).

Single use stone retrieval balloons

Please provide your Indications for Use below.

The Retrieval Balloon is indicated for use endoscopically to remove stones from biliary system, or to facilitate injection of contrast medium while occluding the duct with the balloon. The device is for adult use only.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary(21CFR 807.92)

1. Submitter's information

Name: Zhejiang Chuangxiang Medical Technology Co., LTD.
Address: Room 101-1, 201-1, 301, 401, Building 50, No.650 Hongfeng Road, Donghu Street, Linping District, Hangzhou City,311100 Zhejiang Province, P.R. China.
Contact person: Lucius.Long
Email： lucius.long@med-nova.com
Telephone: 86-571-89167088
Fax: 86-571-89167086

2. Date of Submission

25-September- 2025

3. Device Identification

510(k) Number: K253132
Trade/Device Name: Single use stone retrieval balloons
Regulation name: Biliary catheter and accessories
Regulation class: II
Classification name: Biliary catheter and accessories
Regulation number:876.5010
Product code: FGE

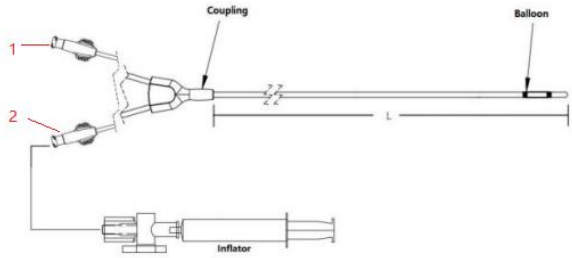
4. Predicative device identification

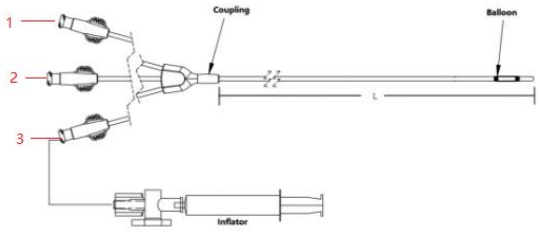
510(k) Number: K211021
Device Name: Sterile Biliary Stone Retrieval Balloon Catheter, Retrieval Balloon / short-wire compatible
Product Code: FGE

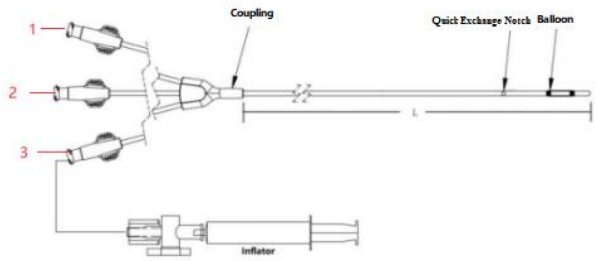
5. Device description

The proposed device Single use stone retrieval balloons includes Stone Retrieval Balloon, inflation pump and two-way valve. Stone Retrieval Balloon is commonly used in traditional ERCP surgery with a long guidewire.
The proposed Single use stone retrieval balloons is comprised of a natural latex balloon mounted at the distal end of a Pebax catheter with three internal lumens for ballooning, guidewire and contrast medium. The internal lumen for ballooning is used to inflate/deflate the balloon. Multiple syringes are included with the packaging, allowing balloon inflation to a specific diameter.

Following insufflation, the balloon surface lies flat against the bile duct wall, enabling efficient and complete cleaning of the bile duct. A separate lumen is designed for a 0.035 inch guidewire. Another separate lumen is designed for contrast agent.
The balloon can be inflated to 8.5 mm, 12 mm, 15 mm and 18 mm diameters using the inflation pump and be kept in an inflated state by two-way valve. Balloon can be inflated to two or three distinct sizes if a different diameter is needed without having to exchange devices. During stone removal process, the balloon can be filled to removal multiple stones in the biliary tract.
There are two developing rings placed at the distal and proximal ends of the balloon providing high fluoroscopic visualization of the balloon location.

Model	Diagram of structure	Differences in Design	Clinical Procedures
D Double cavity	 1. Guide wire chamber catheter seat; 2. Balloon catheter seat;	The double cavity model included the Balloon catheter seat and the Guide wire chamber catheter seat without the injection cavity.	The Balloon catheter seat was connected to the inflator pump for inflating the balloon, and the Guide wire chamber catheter seat was used for inserting the guide wire. The guide wire is inserted from distal end of sheathing to guide wire chamber catheter seat.

T Three-cavity	 1. Injection chamber catheter holder; 2. Guide wire chamber catheter seat; 3. Balloon catheter seat;	The three cavities model included Balloon catheter seat, Guide wire chamber catheter seat and Injection chamber catheter holder.	The Balloon catheter seat was connected with the inflator pump to inflate the balloon, the Guide wire chamber catheter seat was used for guide wire insertion, and the Injection chamber catheter holder was used for injection of contrast agent. The guide wire is inserted from distal end of sheathing to guide wire chamber catheter seat.

E Fast exchange	 1. Injection chamber catheter holder; 2. Guide wire chamber catheter seat; 3. Balloon catheter seat;	The fast exchange model included Balloon catheter seat, Guide wire chamber catheter seat and Injection chamber catheter holder. A quick exchange notch was arranged at one end of the guide wire cavity near the balloon, which could shorten the time of the guide wire passing through the guide wire cavity.	The Balloon catheter seat was connected with the inflator pump to inflate the balloon, the Guide wire chamber catheter seat was provided with a quick exchange port for rapid insertion of the guide wire, and the Injection chamber catheter holder was used for injection of contrast agent. The guide wire is inserted from distal end of sheathing to quick exchange port or guide wire chamber

			catheter seat.

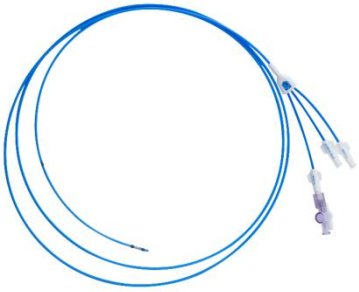
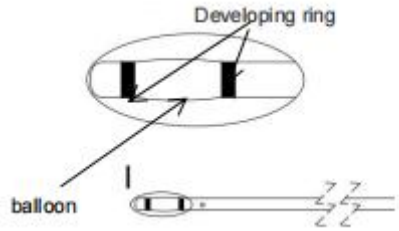
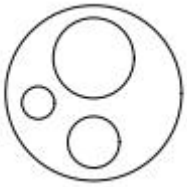
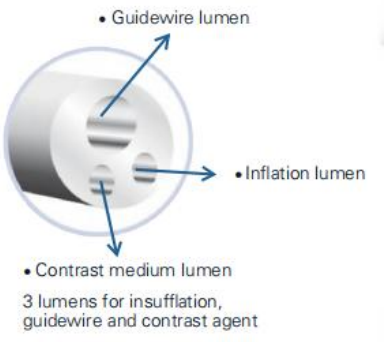
6. Indications for use

The Retrieval Balloon is indicated for use endoscopically to remove stones from biliary system, or to facilitate injection of contrast medium while occluding the duct with the balloon.The device is for adult use only.

7. Comparison of Technological Characteristics with the predicate device:

Item	Proposed device	Predicate device	Comparison to Predicate Devices
Device name	Single use stone retrieval balloons	Sterile Biliary Stone Retrieval Balloon Catheter, Retrieval Balloon / short-wire compatible	N/A
Product code	FGE	FGE	N/A
Regulation No.	876.5010	876.5010	N/A
Manufacturer	Zhejiang Chuangxiang Medical Technology Co., LTD.	Micro-Tech(Nanjing)Co.,Ltd.	N/A
Classification	II	II	Same
Sterilization	EO	EO	Same
Material	Natural Latex/Tantalum/Polyether Block Amide	Natural Latex, Platinum Iridium Alloy, Polyether Block Amide	Different Biocompatibility tests have been done for the difference. Biological risks are acceptable.
Balloon Size	8.5mm/12m/15mm/18mm	9mm/12mm/15mm/18mm	Different Performance tests have been done for the difference. The size different is acceptable

Indications for Use	The Retrieval Balloon is indicated for use endoscopically to remove stones from biliary system, or to facilitate injection of contrast medium while occluding the duct with the balloon.The device is for adult use only.	The Retrieval Balloon Catheter is indicated for use endoscopically to remove stones from biliary system, or to facilitate injection of contrast medium while occluding the duct with the balloon.	Same
Single Use	Yes	Yes	Same
Packaging	Single-use EO sterilized pouch with one device per pouch	Single-use EO sterilized pouch with one device per pouch	Same
Shelf Life	2 years	2 years	Same
Device components	Balloon, Sheathing, Coupling, Injection chamber catheter holder, Guide wire chamber, Balloon catheter seat, Developing ring, Inflator pump Two-way valve	Natural latex balloon, Pebax catheter with three internal lumens, adiopaque bands Multiple syringes	Different It is only different in description.
Lumen number	2 and 3	3	Different The proposed device includes non-injection lumen, which does not increase the risk.
Injection function	The three-lumen device has a catheter with an internal lumens for contrast medium, which is injected into the lumen via the injection chamber catheter holder.	The device has a catheter with an internal lumens for contrast medium, which is injected into the lumen via the injection chamber catheter holder.	Different The proposed device offers non-injection models, which do

	The two-lumen device does not have an injection function.		not increase the risk.
Use environment	This product is intended to be used in medical institutions, such as hospitals and clinics.	This product is intended to be used in medical institutions, such as hospitals and clinics.	Same
Work length	200cm	200cm	Same
Compatible endoscopy work channel	⩾3.2mm	⩾3.2mm	Same
device illustration	 Figue 1 Product photo  Figue 2 Balloon diagram  Figue 3 sheathing anatomy	 Figue 1 Product photo  Figue 2 Balloon diagram  Figue 3 sheathing anatomy	Same

9. Performance Data

Bench testing was performed to support a determination of substantial equivalence. The Single use stone retrieval balloons performs as well as the predicate and is substantially equivalent to the predicate devices.

The following list of bench testing was conducted on the Single use stone retrieval balloons to determine the substantial equivalence with the predicates:
Appearance Test
Dimension Test
Luer connecter
Flow rate
Guidewire Compatibility
Endoscope Compatibility
inflatable volume
Radio-detectablity: The development ring shall be radio-detectable.
Sheath Strength tension
Balloon Strength tension
Tip shaping
Connection Strength Test
sealing performance of connection part
leakage
Non-hydrated: The catheter should not manifest clinically significant hydration when subjected to an aqueous medium
Corrosion resistance
Performance of the Inflator pump
Fast-exchange port performance

10. Sterilization

The proposed device is sold in a sterile package. The proposed device have been sterilized in a validated EO sterilization cycle. The EO residual was measured after sterilization of the device to meet the criteria defined in ISO 11135 Second edition 2014-07-15“Sterilization of Health Care products Ethylene Oxide - Requirements for Development, Validation, and Routine Control of Sterilization processes for Medical Devices [Including: Amendment 1 (2018)]”, and ISO 10993-7 Second Edition 2008-10-15 “Biological evaluation of medical devices Part 7: Ethylene oxide sterilization residuals [Including: Technical Corrigendum 1 (2009), AMENDMENT 1: Applicability of allowable limits for neonates and infants (2019)]”.

11. Shelf Life

The shelf-life of 2 years has been validated through real-time aging testing and the

requirements on packaging for terminally sterilized medical device per ISO 11607-1 Second Edition 2019-02 and ISO 11607-2 Second Edition 2019-02 are also met. The test result can imply that the subject devices can provide and maintain a sterile barrier and its intended performance for at least the claimed shelf life.

12. Biocompatibility

The Biocompatibility testing was performed to show that all patient contacting materials meet applicable biocompatibility standards per ISO 10993-1:2018 and the FDA guidance: Use of International Standard ISO 10993-1 "Biological evaluation of medical devices- Part 1: Evaluation and testing within a risk management process".
The cytotoxicity, sensitization and intracutaneous reactivity were performed to show that the proposed devices are biocompatible.

13. Conclusions

There are no significant differences between the proposed device and the predicate device, the proposed device doesn't raise any new issues of safety and effectiveness. From a clinical perspective and comparing design specifications, the proposed device Single use stone retrieval balloons is substantially equivalent to Micro-Tech(Nanjing)Co.,Ltd. currently marketed Sterile Biliary Stone Retrieval Balloon Catheter, Retrieval Balloon / short-wire compatible.